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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/762,715 | 01/22/2004 | Kristian DiMatteo | 10123/03601 | 5203 |

7590 09/29/2006

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EXAMINER

GRAY, PHILLIP A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3767 | |

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/762,715 | DIMATTEO ET AL. |
| | Examiner | Art Unit |
| | Phillip Gray | 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 July 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5,7-19 and 21-24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-5,7-19 and 21-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

This office action is in response to applicant's communication of 7/6/2006.

Currently claims 1-5, 7-19, and 21-24 are pending and stand rejected below. Claims 6 and 20 were previously cancelled.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 7-19, and 21-24 have been considered but are moot in view of the new ground(s) of rejection. The claims as amended do not distinguish themselves over the prior art of record, See rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-19, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binard et al. (U.S. Patent Number 4,142,525) in view of Crump et al. (U.S. Patent Number 6,227,200). Binard et al. discloses a syringe assembly with a means for limiting the amount of pressure generated by the pumping of the fluid (see figures 4-11, and 14). Binard discloses a connector (20, 50) for injecting fluid to a catheter (c') comprising an attached portion (52) adapted to fluidly couple to a source of pressurized fluid (22), an elongated tubular hypotube component, bypass element (38), fluidly connected to the attachment portion which is adapted to connect to a contrast media power injection system(22), the bypass element being adapted to open a pressure actuated safety valve (67) of a venous catheter (c' at figure 4), and an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level (at figures 9-11).

Binard discloses an elongated tubular component (36, 38) with outlet that has a diameter selected to fit in a flow opening of the valve of the catheter and located distally of the valve. Binard also discloses a bypass element that directs fluid into a catheter so the fluid passes through the catheter without passing through the valve, and with an overpressure control element comprising a pressure relief valve that has a extended tube controlled failure element that fails when the fluid pressure reaches a threshold level (figures 9 and 10). Further Binard discloses an external collection jacket disposed

around the overpressure-controlling element (figures 11 and 14). Binard also discloses a threshold level less than the burst pressure of a catheter attached to the connector. (See paragraphs beginning at column 5, line 23 through columns 5, and line 57)

Crump discloses a "duckbill" type valved fluid coupler with an elongate tube (408) a valve (424) in a catheter assembly (see figures 5A, 5B) so that fluid passes through the fluid coupler without passing through the valve and will permit fluid to pass into the catheter without impinging on the valve.

Binard discloses the claimed invention except for the valve type that permits fluid to flow without impinging the valve. Crump teaches that it is known to use a valve type that permits fluid to flow without impinging the valve as set forth in paragraphs beginning at columns 3-11 specifically discussing figures 5a and 5b, to provide a valve and manifold that minimizes the amount of air drawn into the device and withdrawn will maintain isolation between the catheter tip and the airway through the manifold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluid connector as taught by Binard with a valve type that permits fluid to flow without impinging the valve as taught by Crump, since such a modification would provide the fluid connector with valve type that permits fluid to flow without impinging the valve for providing a valve and manifold that minimizes the amount of air drawn into the device and withdrawn will maintain isolation between the catheter tip and the airway through the manifold.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binard et al in view of Crump et al. Binard in view of Crump discloses the claimed

invention except for the threshold pressure levels between approximately 300 p.s.i. to 40 p.s.i. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have threshold pressure levels between approximately 300 p.s.i. to 40 p.s.i., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It would have involved only routing skill in the art to adjust the threshold pressure level to be less than a burst pressure of a catheter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons